

PATENT

Attorney Docket No. CONLINCO-04286

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Asgeir Saebo *et al.*
Serial No.: 09/544,084
Filed: 04/06/2000
Entitled: Conjugated Linoleic Acid Compositions

Group No.: 1617
Examiner: Wang, S.

**TRANSMITTAL OF APPEAL BRIEF
(PATENT APPLICATION - 37 CFR § 192)**

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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Dated: February 28, 2005

By:

Mary Ellen Waite

Sir or Madam:

1. Transmitted herewith, in triplicate, is the APPEAL BRIEF in this application, with respect to the Notice of Appeal mailed on November 24, 2004 and received in the Mail Room on November 29, 2004.

2. STATUS OF APPLICANT

This application is on behalf of
other than a small entity.

3. FEE FOR FILING APPEAL BRIEF

Pursuant to 37 CFR § 1.17(g), the fee for filing the Appeal Brief is:

Fee for Filing Appeal Brief \$500.00

4. EXTENSION OF TERM

The proceedings herein are for a patent application and the provisions of 37 CFR § 1.136 apply.

Applicant petitions for a one month extension of time under 37 CFR § 1.136
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Fee for Extension of Time \$120.00

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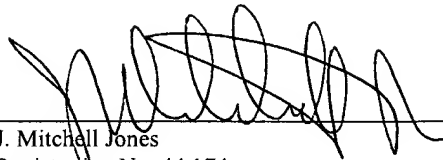
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7. FEE DEFICIENCY

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Dated: February 28, 2005

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Asgeir Sæbo *et al.*

Serial No.: 09/544,084

Group No.: 1617

Filed: 04/06/00

Examiner: Wang, S.

Entitled: CONJUGATED LINOLEIC ACID COMPOSITIONS

APPELLANTS' BRIEF

APPEAL NO.:

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P.O. Box 1450
Alexandria, VA 22313-1450

Dated: February 28, 2005By: 

Mary Ellen Waite

Sir:

This Brief is in furtherance of the Notice of Appeal filed November 29, 2004.

The fees required under § 1.17(h) and any required Petition for Extension of
Time for filing this Brief and fees therefore are dealt with in the accompanying
TRANSMITTAL OF APPEAL BRIEF.

This Brief is transmitted in triplicate. [37 C.F.R. § 1.192(a)].

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This Brief contains these items under the following headings and in the order set forth below [37 C.F.R. § 1.192(c)]:

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I. REAL PARTY IN INTEREST

The real party in interest is Natural ASA, a Norwegian Corporation.

II. RELATED APPEALS AND INTERFERENCES

U.S. Patent Application Serial No. 09/132,593, filed August 11, 1998, is presently on appeal and is related to the present application. There are no other related appeals or interferences known to Appellants, Appellants' legal representative, or the Assignee.

III. STATUS OF THE CLAIMS

Claims 1 - 30 were filed in the original application. During prosecution of the application, Claims 19-30 were canceled. Claims 1-18 and 31 have been rejected by the Office in the Final Office Action dated August 25, 2004. Therefore, Claims 1-18 and 31 are pending in this appeal. No other claims are pending. Thus, Appellants appeal the Final Office Action of August 25, 2004. The Claims, as they now stand, are set forth in Appendix A.

IV. STATUS OF THE AMENDMENTS

Appellants' Response to the Office Action filed on May 7, 2004, has been entered per the Office Action dated August 25, 2004. Amendments to the claims that were made in the May 7, 2004 Response were acknowledged in the Final Office Action dated August 25, 2004. Thus, there are no pending amendments not entered into the record.

V. SUMMARY OF THE INVENTION

This invention relates to the field of nutrition and the supplementation of feedstuffs and food with alkyl esters of conjugated linoleic acid. In particular, methods for producing food products comprising conjugated linoleic acid esters are provided. A method for producing a food product containing conjugated linoleic acid esters comprising providing linoleic acid esters, an alcoholate catalyst, and a foodstuff; treating the linoleic acid esters with the alcoholate catalyst to provide conjugated linoleic acid esters; and combining the foodstuff with the conjugated linoleic acid esters to produce a food product is described, for example, in Example 10. Linoleic acid esters derived from oils selected from the group consisting of safflower, sunflower, and corn oil are described, for example, in Examples 1, 2, 3, 4, 7, 8, 9, and 17, and within the Specification at pages 12 and 18-19. Alcoholate catalysts selected from the group consisting of sodium methyllate, potassium methyllate, sodium ethyllate, and potassium ethyllate are described, for example, in Examples 17 and 18, and in the Specification at pages 8, and 18-19. Treating conjugated linoleic acid esters with an adsorbing agent, providing an antioxidant, and combining the antioxidant with the conjugated linoleic acid esters and the foodstuff to produce a food product is described, for example, in Examples 16, 17 and 18, and in the Specification at pages 22-24. An antioxidant selected from the group consisting of α -tocopherol, β -tocopherol, lecithin, ascorbylpalmitate, and BHT is described, for example, in Example 15, and in the Specification at pages 5, 21, and 23-24. Treating conjugated linoleic acid esters under conditions such that the volatile organic compound content of the conjugated linoleic acid esters is less than 5 ppm after storage is described, for example, in Examples 12, 13, and 16, and in the Specification at pages 21-25.

VI. ISSUES

There are two issues involved in the present appeal:

Issue 1 – Whether Claims 1-18 and 31 are obvious under the judicially created doctrine of obviousness-type double patenting over claims 9-16 of U.S. Patent No. 6,015,833 (hereinafter, “the Sæbo patent”) in view of U.S. Patent No. 5,760,082 (hereinafter, “the Cook patent”); and

Issue 2 – Whether Claims 1-18 and 31 are obvious over the Cook patent in view of WO97/18320 (hereinafter, “the Cain patent”) and U.S. 3,162,658 (hereinafter, “the Baltes patent”) in further view of U.S. 5,885,594 (hereinafter, “the Nilsen patent”).

VII. GROUPING OF CLAIMS

Claims 1-18 and 31 stand or fall together.

VIII. ARGUMENT

A. Issue 1 - Claims 1-18 and 31 Are Not Obvious Under The Judicially Created Doctrine Of Obviousness-Type Double Patenting.

Claims 1-18 and 31 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 9-16 of the Sæbo patent in view of the Cook patent. The Examiner asserts that the Sæbo patent claims a food product containing conjugated linoleic acid, and that the Cook patent teaches that the derivative of conjugated linoleic acid, including esters, are similarly useful as the free acid in food products (1st Office Action, page 3).

However, the doctrine of obviousness-type double patenting requires that there be a common relationship of **inventorship** and/or **ownership** of two or more patents or applications

(see MPEP §804). Moreover, since the doctrine seeks to avoid unjustly extending patent rights at the expense of the public, the focus of any double patenting analysis is necessarily on the **claims** in the multiple patents or patent applications involved in the analysis (see MPEP §804). Since the Cook patent does not have either inventorship or ownership in common with the present application, this doctrine cannot apply. Moreover, the Examiner combined the **disclosure** in the Cook patent with the **claims** of the Sæbo patent, which is an incorrect analysis under the doctrine. Therefore, the Applicants the rejection of the claims on this basis should be withdrawn.

B. Issue 2 - Claims 1-18 And 31 Are Not Obvious Over The Combination Of The Cook, Baltes And Nilsen Patents.

Claims 1-18 and 31 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over the combination of the Cook, Baltes, and Nilsen patents. A *prima facie* case of obviousness requires the Office to cite a reference, or combination of references, that (a) discloses all of the elements of the claimed invention, (b) provides a suggestion or motivation to one of skill in the art to combine the elements to yield the claimed combination, and (c) provides a reasonable expectation of successfully carrying out the claimed combination. Failure to establish any one of the three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles the Applicants to allowance of the claims at issue.¹ The Office has failed to establish a *prima facie* case of obviousness because 1) the Office has not provided a motivation to combine the references; 2) the Office is applying hindsight reconstruction; 3) the Office is improperly disregarding the Sæbo Declaration; and 4) the Office is misapplying the law.

¹ See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

1. There Is No Motivation To Combine The References In The Manner Indicated By The Office

The Office fails to provide suitable evidence of a motivation to combine the Cook, Baltes, and Nilsen patents, thus a *prima facie* case of obviousness has not been established. The Office has made the following statements:

The "well-known" conclusion is supported by the teaching of Baltes et al. Cain et al. The instant claims are drawn to a method of making CLA and using CLA in food product. If the method of making CLA herein claimed is well-known, and using CLA in food product is well-known, the claimed method would have been obvious. Office Action dated February 11, 2004; Paper Number 20040206Feb2004 OA pages 5-6.

In the instant situation, the prior art teaches the employment of CLA as food ingredient was known, and using alcoholic catalyst for making CLA was also known, the employment of CLA made by alcoholic catalyst for food would have been obvious to one of ordinary skill in the art. *There is no need of invoking high level of skill in the art.* Office Action dated August 25, 2004; Paper Number 20040819; pages 5; emphasis added.

Applicants respectfully submit that these statements are **misapplications of the law**.

The Office's basic argument is that **if** two things are well known (alcoholate catalysis and CLA in food), **then** the combination of the two things is well known (using CLA produced by alcoholate catalysis in food). Indeed, the Office goes so far as to state that in such circumstances, "[t]here is no need of invoking high level of skill in the art." This reasoning is completely devoid of any motivation to combine. Indeed, the only reasoning provided is that the two things are "well known."

The Federal Circuit has expressly forbidden this approach:

The Board did not . . . explain what specific understanding or technological principal within the knowledge of one of ordinary skill in the art would have suggested the combination. **Instead, the Board merely invoked the high level of skill in the art.** If such a rote invocation could suffice to supply a motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable

technological advance. Instead, in complex scientific fields, the Board could routinely identify the prior art elements in an application, invoke the lofty level of skill, and rest its case for rejection. To counter this potential weakness in the obviousness construct, the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness (Emphasis added).

In re Rouffet, 47 USPQ2d 1453 (Fed. Cir. 1998). In the instant application, the sole basis for combination is the allegedly "well-known" status of two separate concepts. The Examiner's combination on this basis is inadequate as a matter of law.

The Office has also failed to analyze the invention as a whole. When analyzed as a whole, the use of a method for making CLA is non-obvious when the CLA is going to be utilized for food. "That each element in a claimed invention is old or unpatentable does not determine the nonobviousness of the claimed invention as a whole." *Custom Accessories v. Jeffrey-Allan Industries Inc.*, 807 F.2d 955, 1 USPQ 2d 1196, 1198 (Fed. Cir. 1986); See also *Brantingson Fishing Equipment Co. v. Shimano American Corp.*, 9 USPQ 2d 1669, 1672 (Fed. Cir. 1988). Put another way: "Only God works from nothing. Men must work with old elements." *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 225 USPQ 26, 31 n. 3 (Fed. Cir. 1985) (quoting from Markey, "Why Not the Statute," 65 JPOS 331, 333-334 (1983)).

The *Fromson* case is particularly relevant here. In that case, the inventor developed a process for photolithography using 1) aluminum as a substrate, 2) oxide coatings by anodization, 3) silication, and 4) application of light-sensitive resins. The district court correctly found that each of these elements individually were known in the art - but incorrectly concluded, on the basis of the unpatentability of each element, that the combination of these steps was unpatentable. On appeal, the Federal Circuit pointed to the "fundamental error" of the district court, noting: "At no point did the court indicate, nor does the record indicate, a basis on which it

can be said that the making of that combination would have been obvious when it was made."

Fromson, supra at 31.

Likewise, in the instant case there has been showing of why one would be motivated to use the alcoholate catalysis process in the production of CLA for food uses as claimed. Absent a motivation to combine the references, the Office has not established a prima facie case of obviousness.

The Office contended that the *Custom Accessories, Brantingson Fishing Equipment Co.*, and *Fromson* cases are not relevant to the instant invention. In particular, the Office stated:

[T]he cited cases, *Fromson* in particular, are not suitable for the instant situation. Particularly, In *Fromson*, each and every steps and the materials involved are closely related in terms of time and space, each step would affect the others. It would be impossible to separate the step and materials involved. In the instant situation, the two ingredients involved, CLA and food could be made separately in term of space and time. Method of making one ingredients would not affect the other. Office Action dated August 25, 2004; Paper Number 20040819; pages 6.

The Applicants contend that the Examiner is misunderstanding the message of the *Fromson* case. In particular, the *Fromson* case holds that the unpatentability of a set of elements does not render the combination of the references obvious. As noted, in the instant case, there has been showing of why one would be motivated to use the alcoholate catalysis process in the production of CLA for food uses as claimed. As such, the *Fromson* case is particularly relevant because the Office is attempting to do precisely what the *Fromson* court deemed unacceptable. Accordingly, the Office has not established a prima facie case of obviousness and that the claims should be passed to allowance.

The Office further contended:

As to Baltes' teaching, the examiner restates that Baltes reference does not expressly limited to produce CLA for coating. Note question under 35 U.S.C. 103 is not merely what reference expressly teach, but what they

would have suggested to one of ordinary skill in the art at the time the invention was made; all disclosures of prior art, including unpreferred embodiments, must be considered. In re Lamberti and Konort (CCPA), 192 USPQ 278. Contrary to applicants' assertion, Baltes states "The invention relates to a process for substantially complete catalytic conversion of compounds of unconjugated polyethenoid acid into compounds of conjugated enthenoid acid." (column 1, lines 13-16). "It will be appreciated from the above that this invention is not limited to the materials, steps, conditions and other details specifically described above and can be carried out with various modification. Thus, it will be understood that the process of this invention is broadly applicable to any unconjugated polyethenoid acid compounds and products containing them." (column 8, lines 20-50, examiner emphasis added). Baltes particularly claims the process for the catalytic isomerization of unconjugated polyethenoid fatty acid compounds to conjugated isomers using alkali metal monohydric alcoholate (see, particularly, claim 10-12). Office Action dated August 25, 2004; Paper Number 20040819; pages 4-6-7.

The Office takes this statement completely out of context. As pointed out in the Declaration of Asgeir Sæbo (discussed in more detail below), Baltes teaches the use of alcoholate catalysts to produce CLA for use in industrial products such as paints and varnishes. **Baltes fails to address the use of CLA made by these methods in food products.** Thus, a person of ordinary skill in the art reading Baltes would interpret the statement quoted by the Office as teaching that the processes of Baltes could be used to produce CLA for use in industrial type products, not food products. As such, this so-called "suggestion" from Baltes cannot serve as motivation to combine the references.

2. The Office's Reasoning Demonstrates Hindsight Reconstruction

The Office has applied hindsight reconstruction to combine the Cook, Baltes, and Nilsen patents. As noted in the *In re Rouffet* case cited above, hindsight reconstruction is not permitted. The Office, however, relies upon *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971) for the proposition that:

[I]t must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

To the extent that this 1971 C.C.P.A. case appears to condone hindsight reconstruction when providing a motivation to combine references, the Federal Circuit has *sub silentio* overruled this proposition, and has emphatically stated that hindsight reconstruction is not proper (as detailed below).

The Federal Circuit has repeatedly warned against using hindsight reconstruction as a test of obviousness. A few examples of such cases include: *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988) ("One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention"); *Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720 (Fed. Cir. 1990) (The inappropriateness of hindsight as a test of obviousness was, in point of fact, discovered, and articulated lucidly, over three centuries ago, by Milton, who, in *Paradise Lost* Part IV, L. 478-501, stated "The invention all admired, and each how he To be the inventor missed; so easy it seemed, Once found, which yet unfound would have thought, Impossible!"); *Heidelberger Druckmaschinen AG v. Hantscho Commercial Products, Inc.*, 21 F.3d 1068 (Fed. Cir. 1993) ("The motivation to combine references can not come from the invention itself"); *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566 (Fed. Cir. 1996) ("To draw on hindsight knowledge of the patented invention, when the prior art does not contain or suggest that knowledge, is to use the invention as a template for its own reconstruction-an illogical and inappropriate process by which to determine patentability"); *W.L. Gore & Assocs., Inc. v. Garlock Inc.*, 721 F.2d 1540 (Fed. Cir. 1983) ("To imbue one of ordinary skill in the art with the

knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of hindsight syndrome wherein that which only the inventor taught is used against its teacher ..."). Accordingly, to the extent the Office has admitted reliance on hindsight reconstruction, that reliance is misplaced as a matter of law.

3. The Office Has Ignored Evidence Presented By The Applicants That Establishes That Patentable Weight Should Be Given To The Combination Of Adding Alcoholate Catalyzed CLA To Food Products.

Applicants **have provided evidence** as to why a method that uses CLA produced by alcoholate catalysis to make food products in non-obvious. The Office, however, has ignored the evidence presented by the Applicants establishing that patentable weight should be given to the combination of adding alcoholate catalyzed CLA to food products. In particular, in reference to the patentability of the claims, the Office stated:

[R]egarding the limitation about the method to obtain the conjugated linoleic acid, note a method of making ingredients is not seen to render patentable weight to a method which employs such ingredients, absent evidence to the contrary." Office Action dated July 16, 2003; Paper Number 20030716; page 4.

Applicants first note that this statement ignores the actual language of the claims, which specify the particular step of using an alcoholate catalyst. This is contrary to the Office's statement that the claims only employ such ingredients. Applicants fail to see how the Office can simply ignore a process step and reason that a specific step cannot provide patentable weight to a method claim. The Office provided no legal authority on this point. Applicants are not aware of any such legal precedent.

Furthermore, Applicants **have provided** evidence that it is not obvious to simply use a process that was previously used for the production of CLA for industrial uses with a method for food production. This evidence is provided by the Declaration of Asgeir Sæbo (provided at Appendix B). As detailed in the Sæbo Declaration, none of the references teach or suggest using CLA isomerized with alcoholate catalysts in food products. Furthermore, as explained by Dr. Sæbo, the Baltes patent discloses the use of oils with high levels of triunsaturated fatty acids. These oils are not generally suitable for the production CLA for oral consumption. Thus, the Office's attempt to claim that the compositions of Baltes could be used in a food product is misguided.

In fact, the Baltes reference indicates that the uses the products are suited for are industrial in nature. In particular, Baltes et al. describe methods for producing conjugated linoleic acids described as being "valuable industrial products" for use in formation of "light colored polymers," for use as "ingredients of lacquers or coating compositions" or as "ingredients of plasticizers" and as "reaction components in the preparation of resins" (Baltes et al., *col. 9, ll. 47-60*). As such, the Baltes reference is directed to the production of substitutes for tung oil that are not suitable for consumption. The tung oil substitutes described in Baltes et al., are intended for industrial uses such as for drying oils, varnishes, and lacquers. Consequently, Baltes et al., describes methods for producing toxic oil substitutes for non toxic oils (tung oil). Nothing in the Baltes et al. reference teaches or suggest the desirability--or even applicability--of using the methods disclosed therein to produce food products.

Thus, Applicants **have provided evidence** as to why a method that uses CLA produced by alcoholate catalysis to make food products is non-obvious. The Examiner must respond to all of the arguments and evidence presented by Applicants. The MPEP states that:

Office personnel should consider all rebuttal arguments and evidence presented by applicants. . . . *In re Beattie*, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992). . . . **Office personnel should avoid giving evidence no weight**, except in rare circumstances. *Id.* See also *In re Alton*, 76 F.3d 1168, 1174-75, 37 USPQ2d 1578, 1582-83 (Fed. Cir. 1996).

* * *

A determination under 35 U.S.C. 103 should rest on **all the evidence** and should not be influenced by any earlier conclusion. See, e.g., *Piasecki*, 745 F.2d at 1472-73, 223 USPQ at 788; *In re Eli Lilly & Co.*, 902 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990). Thus, once the applicant has presented rebuttal evidence, Office personnel should **reconsider** any initial obviousness determination in view of the entire record. See, e.g., *Piasecki*, 745 F.2d at 1472, 223 USPQ at 788; *Eli Lilly*, 902 F.2d at 945, 14 USPQ2d at 1743.²

Additionally, the Courts have held as follows:

When *prima facie* obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over An earlier decision should not . . . be considered as set in concrete, and applicant's rebuttal evidence then be evaluated only its knockdown ability. Analytical fixation on an earlier decision can tend to provide the decision with an undeservedly broadened umbrella effect. *Prima facie* obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself. Though the tribunal must begin anew, a final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached . . . upon a different record.³

Furthermore:

If a *prima facie* case is made in the first instance, and if the applicant comes forward with a reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be reweighed.⁴

Accordingly, even if the Office had established a *prima facie* of obviousness in a preceding office action (and Applicants contend that he did not), the Examiner must respond to Applicants

² MPEP §§2144.08; emphasis added).

³ *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976).

⁴ *In re Hedges*, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986).

arguments. The failure to rebut either the arguments or the evidence advanced by the Applicants is reversible error under *In re Alton*, 76 F.3d 1168, 37 U.S.P.Q.2d 1578 (Fed. Cir. 1996).

In *In re Alton*, the applicants submitted a declaration in order to rebut a *prima facie* case of inadequate written description by the Board of Appeals in an earlier appeal. *Id.* at 1173. Instead of addressing the arguments presented in the declaration, the Examiner dismissed the declaration as opinion evidence that was entitled to little weight. *Id.* at 1173-745. The Federal Circuit remanded the case to the Board, holding that the Board committed error in both viewing the declaration as opinion evidence and dismissing the declaration "without an adequate explanation of why the declaration failed to rebut the Board's *prima facie* case" of unpatentability. *Id.* at 1174. These bases for reversal were independent. With respect failure to provide an adequate explanation of why the declaration failed to rebut the *prima facie* case, the Federal Circuit found that:

In sum, the examiner dismissed the Wall declaration and provided only conclusory statements as to why the declaration did not show that a person skilled in the art would realize that Alton had possession of the claimed subject matter in 1983.

Id. at 1176. In particular, the Federal Circuit held that the examiner failed to address specific points made in the declaration concerning modifications of the amino acids sequence of protein. *Id.*

In re Alton is directly applicable to the present facts. Instead of addressing the arguments presented in the Sæbo Declaration, the Office has provided only conclusory statements and failed to address the particular evidence offered in the Declaration. In particular, the Sæbo Declaration provides evidence that:

- "The Baltes patent is not applicable to the present invention because the Baltes patent teaches methods of making CLA and

conjugated linolenic acid (CLnA) for technical purposes such as drying oils and paint varnishes.

- The intended use of the conjugated linoleic acids for technical purposes as opposed to nutritional purposes is further reaffirmed at Column 9, lines 47-60 of Baltes patent where it is stated that "[t]he compounds of conjugated fatty acids obtained by the method of this invention, or mixtures containing these compounds, are valuable industrial products which can be used in many ways. . . . The polymers thus formed can be used as ingredients of lacquers or coating compositions in conventional manners."
- Based on the disclosure of the Baltes, Cook and Lievense patents, one cannot conclude that the CLA resulting from the alcoholate catalysis process is suitable for use in products meant for oral consumption.
- Other disclosure in the Baltes patent also indicates the unsuitability of the methods for the production of edible CLA.
- The Baltes patent describes the conjugation of soybean oil (Examples 1, 2, 6, 8, 9, 10, and 11), cottonseed oil (Example 3), linseed oil (Examples 4 and 5), and fish oil (Example 7), all of which contain high levels of triunsaturated fatty acids. These oils are generally unsuitable for obtaining CLA for nutritional uses because the refinement results in products with substantial amounts of breakdown products and unwanted polymers, especially when conjugated.
- However, it is noted that the use of oils with high levels of triunsaturated fatty acids as starting materials for CLA and CLnA for technical purposes is preferred due to the superior drying properties of conjugated trienes.

The only rebuttal of this evidence is provided in the Office Action dated December 28,

2001. The Examiner's attempted rebuttal, in its entirety, is as follows:

The declaration filed October 18, 2001 [the Sæbo Declaration] is insufficient to overcome the rejection of claims 1-30 set forth above because: the teaching of Baltes et al. is not limited to the particular oil disclosed in the examples therein. Baltes teaches a general method for isomerising unconjugated polyethenoid to conjugated polyethenoid. See, column 1, lines 13-16. The starting material may be any unconjugated polyethenoid compounds or products containing them. See column 8, lines 20-68. Further, applicant appears to argue the employment of the reaction mixture to foodstuff, what is actually in the claims are the compounds, i.e., conjugated linoleic esters. ("to provide conjugated linoleic acid esters", see the claims in the instant application). Office Action dated December 21, 2001; Paper Number 12; page 5.

This response completely fails to respond to any of the points listed above. The Office states that Baltes is not limited to any particular oil. However, this fails to respond to the conclusion advanced by Mr. Sæbo that one skilled in the art would read the application to be directed to oils with high levels of triunsaturated fatty acids because a substitute for Tung oil was being sought. The Office further states that Baltes teaches the use of the resulting polyethenoid compounds for "any" product. However, this statement ignores the evidence advanced that a person of ordinary skill in the art would read Baltes as being directed to use of CLA for technical purposes, such as in paints in varnishes. Finally, the Office, states that "applicant appears to argue the employment of the reaction mixture to foodstuff" and dismisses the argument the claims are allegedly (and mistakenly) to compounds. This is precisely the point and indeed, what is claimed! **The use of the method of Baltes to produce CLA for use in foodstuffs is not obvious. As discussed above, the Examiner has failed to examine the invention as a whole.**

As a result, Applicants respectfully request that the Examiner reconsider the evidence offered in the Sæbo Declaration. This evidence establishes that cited references cannot be properly combined and thus rebuts a prima facie case of obviousness. Accordingly, Applicants respectfully request that the claims be passed to allowance.

4. The Examiner's Citation Of *In re Boesch* Is Inappropriate

The Examiner has cited *In re Boesch*, 205 USPD 215 (CCPA 1980) for the proposition that:

Further, purifying CLA composition by using silica gel (adsorbent) is seen to be obvious since silica gel is well known for purification and separation purpose. Having a limitation of the volatile organic compound (VOC) in food product (whether it the limitation after storage or before storage) is considered an optimization of a result effective parameter, which is

considered within the skill of the artisan. Office Action dated August 25, 2004; Paper Number 20040819; pages 4-5.

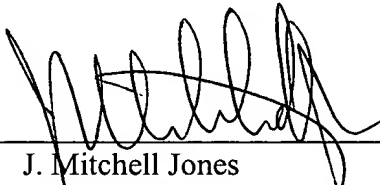
The Examiner is respectfully directed to the MPEP at §2144.05 which states a "particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimization of workable ranges of said variable might be characterized as routine experimentation." The MPEP additionally cites *In re Antonie*, 559 F.2d 618 (CCPA 1997) for the proposition that the failure of the prior art to recognize a result-effective variable results in the nonobviousness of a claimed range. This is contrasted with *In re Boesch*, in which the court held that the prior art suggested proportional balancing to achieve desired results in the formation of an alloy.

In the instant case, the amount of VOC is not a result effective variable, it is a property which results from the proper treatment and handling of the CLA. It is noted, however, the underlying methods of treatment may involve result effective parameters, for example, silica adsorption with particular amounts of silica for the removal of metal ion contaminants. The claims are not limited to the methods and thus the result-effective variable analysis is inactive. Applicants further note that this treatment step is not recognized by the prior art as a treatment method for CLA products and thus, if it were claimed, would actually establish the patentability of the claims.

C. Conclusion

For the foregoing reasons, it is submitted that the Office's rejection of Claims 1-18 and 31 was erroneous, and reversal of the rejection is respectfully requested. Appellant requests either that the Board render a decision as to the allowability of the claims, or alternatively, that the application be remanded for reconsideration by the Office.

Dated: February 28, 2005



J. Mitchell Jones
Registration No. 44,174

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APPENDIX A

CLEAN VERSION OF THE ENTIRE SET OF PENDING CLAIMS

1. (previously amended) A method for producing a food product containing conjugated linoleic acid esters comprising:
 - a) providing:
 - i) linoleic acid esters,
 - ii) an alcoholate catalyst,
 - iii) a foodstuff;
 - b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters; and
 - c) combining said foodstuff with said conjugated linoleic acid esters from step (b) to produce a food product.
2. (original) The method of Claim 1, wherein said linoleic acid esters are derived from oils selected from the group consisting of safflower, sunflower, and corn oil.
3. (previously amended) The method of Claim 1, wherein said alcoholate catalyst is selected from the group consisting of sodium methyllate, potassium methyllate, sodium ethyllate, and potassium ethyllate.
4. (previously amended) The method of Claim 1, wherein step (c) further comprises treating said conjugated linoleic acid esters with an adsorbing agent, providing an antioxidant and combining said antioxidant with said conjugated linoleic acid esters and said foodstuff in step (d) to produce said food product.
5. (previously amended) The method of Claim 4, wherein said antioxidant is selected from the group consisting of α -tocopherol, β -tocopherol, lecithin, ascorbylpalmitate, and BHT.
6. (previously amended) The food product produced according to the method of Claim 1, further comprising an antioxidant selected from the group consisting of lecithin, ascorbylpalmitate, and BHT.

7. (previously amended) A method for producing a food product containing conjugated linoleic acid comprising:

- a) providing:
 - i) linoleic acid esters,
 - ii) an alcoholate catalyst,
 - iii) a foodstuff;
 - b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;
 - c) treating said conjugated linoleic acid esters to provide conjugated linoleic acid;
- and
- d) combining said foodstuff with said conjugated linoleic acid from step (c) to produce a food product.

8. (original) The method of Claim 7, wherein said linoleic acid esters are derived from oils selected from the group consisting of safflower, sunflower, and corn oil.

9. (previously amended) The method of Claim 7, wherein said alcoholate catalyst is selected from the group consisting of sodium methylate, potassium methylate, sodium ethylate, and potassium ethylate.

10. (previously amended) The method of Claim 7, wherein step (d) further comprises treating said conjugated linoleic acid esters with an adsorbing agent, providing an antioxidant and combining said antioxidant with said conjugated linoleic acid and said foodstuff in step (b) to produce said food product.

11. (previously amended) The method of Claim 10, wherein said antioxidant is selected from the group consisting of α -tocopherol, β -tocopherol, lecithin, ascorbylpalmitate, and BHT.

12. (previously amended) The food product produced according to the method of Claim 7, further comprising an antioxidant selected from the group consisting of lecithin, ascorbylpalmitate, and BHT.

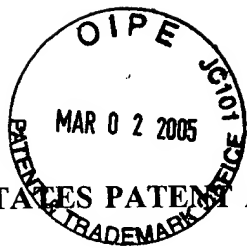
13. (previously amended) A method for producing a food product containing conjugated linoleic acid triglycerides comprising:

- a) providing:

- i) linoleic acid esters,
 - ii) an alcoholate catalyst, and
 - iii) a foodstuff; and
 - b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;
 - c) incorporating said linoleic acid esters into triglycerides to provide triglycerides containing conjugated linoleic acid moieties; and
 - d) combining said foodstuff with said triglycerides containing conjugated linoleic acid moieties from step (c) to produce a food product.
14. (original) The method of Claim 13, wherein said linoleic acid esters are derived from oils selected from the group consisting of safflower, sunflower, and corn oil.
15. (previously amended) The method of Claim 13, wherein said alcoholate catalyst is selected from the group consisting of sodium methyllate, potassium methyllate, sodium ethyllate, and potassium ethyllate.
16. (previously amended) The method of Claim 13, wherein step (d) further comprises treating said triglycerides containing conjugated linoleic acid moieties with an adsorbing agent, providing an antioxidant and combining said antioxidant with said triglycerides and said foodstuff in step (b) to produce said food product.
17. (previously amended) The method of Claim 16, wherein said antioxidant is selected from the group consisting of α -tocopherol, β -tocopherol, lecithin, ascorbylpalmitate, and BHT.
18. (previously amended) The food product produced according to the method of Claim 13 , further comprising an antioxidant selected from the group consisting of lecithin, ascorbylpalmitate, and BHT.
- 19-30. (canceled)
31. (previously presented) A method for producing a food product containing conjugated linoleic acid esters comprising:
- a) providing:
 - i) linoleic acid esters,

- ii) an alcoholate catalyst,
- iii) a foodstuff;
- b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;
- c) treating said conjugated linoleic acid esters under conditions such that the volatile organic compound content of said conjugated linoleic acid esters is less than 5 ppm after storage;
- d) combining said foodstuff with said conjugated linoleic acid esters from step (c) to produce a food product.

APPENDIX B
Declaration of Asgeir Saebo with attachments



PATENT

Attorney Docket No. CONLINCO-04286

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Asgeir Sæbo *et al.*

Serial No.: 09/544,084

Group No.: 1617

Filed: 04/06/00

Examiner: Wang

Entitled: CONJUGATED LINOLEIC ACID COMPOSITIONS

Declaration of Asgeir Sæbo

Assistant Commissioner for Patents
Washington, D.C. 20231

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)	
I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.	
Dated: <u>10-15-01</u>	By: <u>Mary Ellen Wank</u>

I, Dr. Asgeir Sæbo, state as follows:

1. My present position is Director of Research, Natural AS.
2. I have reviewed the above captioned patent application, of which I am an inventor, the Office Action mailed July 23, 2001, and the Cook, Baltes, and Lievens patents cited as prior art.
3. After review of the cited references, I conclude that the references do not teach methods of producing conjugated linoleic acid suitable for oral consumption with alcoholate catalysts. In fact, only one of the cited references, Baltes, teaches the use of alcoholate catalysts for any purpose. It is my understanding that in the Office Action the Examiner states that "[t]he citation of Baltes et al. (U.S. Patent 3,162,658) is to show the level of ordinary skill in the art."
4. Contrary to the Examiner's opinion, the Baltes patent is not applicable to the present invention because the Baltes patent teaches methods of making CLA and conjugated linolenic

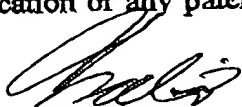
acid (CLnA) for technical purposes such as drying oils and paint varnishes. In particular, Column 1, line 30 of the Baltes patent provides that "[t]he latter ones, namely the unconjugated polyethenoid acids occur in nature in large quantities, while conjugated polyethenoid acids are relatively seldom found in fats and oils of natural origin except for woods oils such as tung oil. The latter compound and also its derivatives are of great technical interest and therefore, many attempts were made to isomerize unconjugated polyethenoid acids to conjugated acids." The Baltes patent is solving the problem of providing substitute conjugated acids for naturally occurring conjugated acid sources such as tung oil. Therefore, the methods of the Baltes patent are intended to produce an oil suitable for the same purposes as tung oil. Tung oil is not edible and the tung tree is listed in the "Poisonous Plant Bibliography" of the United States Food and Drug Administration, Center for Food Safety & Applied Nutrition, Office of Plant and Dairy Food and Beverages. The intended use of the conjugated linoleic acids for technical purposes as opposed to nutritional purposes is further reaffirmed at Column 9, lines 47-60 of Baltes patent where it is stated that "[t]he compounds of conugated fatty acids obtained by the method of this invention, or mixtures containing these compounds, are valuable industrial products which can be used in may ways. . . . The polymers thus formed can be used as ingredients of lacquers or coating compositions in convential manners." Based on the disclosure of the Baltes, Cook and Lievense patents, one cannot conclude that the CLA resulting from the alcoholate catalysis process is suitable for use in products meant for oral consumption.

5. Other disclosure in the Baltes patent also indicates the insuitability of the methods for the production of edible CLA. Conjugated acids are inherently unstable. Stability is related to the number of double bonds. The Baltes patent describes the conjugation of soybean oil (Examples 1, 2, 6, 8, 9, 10, and 11), cottonseed oil (Example 3), linseed oil (Examples 4 and 5), and fish oil (Example 7), all of which contain high levels of triunsaturated fatty acids. These oils are generally unsuitable for obtaining CLA for nutritional uses because the refinement results in products with substantial amounts of breakdown products and unwanted polymers, especially when conjugated. However, it is noted that the use of oils with high levels of triunsaturated fatty acids as starting materials for CLA and CLnA for technical purposes is preferred due to the superior drying properties of conjugated trienes.

PATENT

Attorney Docket No. **CONLINCO-04286**

6. I further declare that all statement made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



Dr. Asgeir Sæbo

Date: Oct 12 2001